HIGH RISK ARTHRITIS, MUSCULOSKELETAL AND SKIN DISEASES RESEARCH

Release Date: August 18, 1999

RFA: AR-99-008

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Application Receipt Date: October 13, 1999

THIS RFA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS RFA.

PURPOSE

The purpose of this initiative is to broaden the base of inquiry in fundamental biomedical and biomedical technology research by encouraging applications for research projects that involve an especially high degree of innovation and novelty and, therefore, require a preliminary test of feasibility. The research projects proposed under this Request for Applications (RFA) may involve substantial experimental risks such that their potential for highly significant outcomes may be difficult to judge by the standard criteria used in evaluating investigator initiated (R01) proposals. Preliminary data is not required. The work proposed may not overlap with the aims of currently supported projects in which the Principal Investigator has participated during the last five years. Proposed projects must support the mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

Two kinds of experienced investigators are sought. First, established investigators in arthritis or musculoskeletal or skin diseases are encouraged to present a proposal for testing the feasibility of a novel idea, resource or technology. The project should represent a clear and distinct departure from the investigator's ongoing research. Second, established investigators with no previous work in arthritis or musculoskeletal or skin diseases are encouraged to apply their expertise to research relevant to arthritis or musculoskeletal or skin diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, High Risk Arthritis, Musculoskeletal and Skin Diseases Research, is related to the priority area of chronic diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0 or Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Foreign organizations and institutions are not eligible. Participation in the program by investigators at minority institutions is strongly encouraged.

The work proposed may not overlap with the aims of currently supported projects in which the Principal Investigator has participated during the last five years. (Information on such projects is to be provided as part of the Principal Investigator's Biographical Sketch, as described below under Application Procedures.)

Investigators who have questions about eligibility should contact one of the program officials listed under INQUIRIES.

MECHANISM OF SUPPORT

Research projects will be supported with the exploratory/developmental research grant (R21). Applicants may request up to $50,000 (direct costs) per year for up to two years. These awards are not renewable. If desired, the specific aims of the R21 project may be incorporated into a research project grant application (R01) submitted prior to the termination of the R21 award. This RFA is a one-time solicitation.

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts. Complete and detailed instructions and information on Modular Grants can be found at http://grants.nih.gov/grants/funding/modular/modular.htm .

FUNDS AVAILABLE

It is anticipated that for FY 2000, approximately $750,000 total costs will be available for the first year of support for this initiative. Award of grants is contingent upon the receipt of such funds for this purpose. It is anticipated that up to 12 new grants will be awarded under this program. The specific number to be funded will depend on the merit and scope of the applications received and on the availability of funds. Direct costs will be awarded in modules of $25,000, less any overlap or other necessary administrative adjustments. Facilities and Administrative costs will be awarded based on the negotiated rates. Applicants may request up to two years of support.

RESEARCH OBJECTIVES

The NIAMS seeks to broaden the base of inquiry in fundamental biomedical and biomedical technology research by encouraging research projects that involve a high degree of innovation and novelty. Because innovative projects may require a preliminary test of feasibility, this initiative will provide short-term support for such preliminary work. Each research plan should begin with a short paragraph describing how the proposed project represents a high degree of innovation and novelty that does not overlap with recently funded research.

The projects must support the NIAMS mission as detailed in the NIAMS World Wide Web home page, which can be found at http://www.nih.gov/niams/. In brief, the NIAMS supports research in (a) rheumatic diseases; (b) bone biology and diseases (e.g., osteoporosis, Paget's disease); (c) skin biology and skin diseases; (d) autoimmune diseases (e.g., lupus); (e) connective tissue diseases; (f) musculoskeletal diseases, injuries and disorders; (g) muscle diseases (e.g., muscular dystrophy); exercise physiology and musculoskeletal fitness; (h) sports injuries; (i) occupational diseases and injuries; and (j) bioengineering.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the

"NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994. This information is available on the internet at http://grants.nih.gov/grants/guide/notice-files/not94-100.html.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that children must be included in all human subjects research conducted or supported by the NIH unless there are scientific or ethical reasons not to include them. The goal of the policy is to increase the participation of children in research to obtain appropriate data. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts, March 6, 1998. Further information is available on the internet at http://grants.nih.gov/grants/funding/children/children.htm.

Investigators also may obtain copies of the policies on "Inclusion of Children as Participants in Research Involving Human Subjects" from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below. These forms are available at most institutional offices of sponsored research; from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, Email: grantsinfo@nih.gov; and on the internet at http://grants.nih.gov/grants/funding/phs398/phs398.html.

The RFA label found in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. The RFA label and line 2 of the application should both indicate the RFA number. Failure to use this label could result in delayed processing of the application

such that it may not reach the review committee in time for review. In addition, the RFA title, High Risk, Arthritis, Musculoskeletal and Skin Diseases Research, and number, AR-99-008, must be typed on line 2 of the face page of the application form and the YES box must be marked.

The sample RFA label available at:
http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

BUDGET INSTRUCTIONS

Modular grant applications will request direct costs in $25,000 modules, up to a total direct cost request of $50,000 per year. A typical modular grant application will request the same number of modules in each year.

The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE - Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $50,000) and Total Costs [Modular Total direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Use a Modular Grant Budget Narrative page.
(See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.)
At the top of the page, enter the total direct costs requested for each year.

o Under Personnel, List key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the letter of intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm.

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years;
- List selected peer-reviewed publications, with full citations.

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

APPLICATIONS NOT CONFORMING TO THESE GUIDELINES WILL BE CONSIDERED UNRESPONSIVE TO THIS RFA AND WILL BE RETURNED WITHOUT FURTHER CONSIDERATION.

Submit a signed typewritten original of the application and three signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC-7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U - MSC 6500
Bethesda, MD 20892-6500

In order not to delay review, it is important that applicants comply with this request.

Applications must be received by October 13, 1999. If an application is received after that date, it will be returned to the applicant without review. Only one R21 grant application may be submitted by a Principal Investigator.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by NIAMS. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and under a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the NIAMS Advisory Council.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. For this initiative, the proposed project must have the potential for developing ground-breaking technology or methodology that may lead to significant expansion of biomedical research horizons, precipitate a paradigm shift in research, or lead to substantial improvements in human health. In the written review, comments on the following aspects of the application will be made in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in the assignment of the overall score.

(1) Significance. Does the proposed study clearly not overlap with recently funded research? Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the investigator acknowledge potential problem areas and consider alternative tactics?

(3) Innovation. Does the project employ novel concepts, approaches or method?
Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The initial review group will also examine the provisions for the protection of human and animal subjects, the safety of the research environment, and conformance with the NIH Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research.

The personnel category will be reviewed for appropriate staffing based on the requested percent effort. The direct costs budget request will be reviewed for consistency with the proposed

methods and specific aims. Any budgetary adjustments recommended by the reviewers will be in $25,000 modules. The duration of support will be reviewed to determine if it is appropriate to ensure successful completion of the requested scope of the project.

AWARD CRITERIA

The following will be considered in making funding decisions:

o Scientific merit of the proposed project as determined by peer review
o Importance of the area to NIAMS research
o Availability of funds; and
o Potential for ground-breaking, precedent setting significance of the proposed research, with particular emphasis on novel and innovative approaches that clearly require additional preliminary data for their value to be established.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to one of the following persons, according to scientific area:

Orthopedics and Bioengineering

Dr. James S. Panagis
45 Center Drive, Room 5AS-37K
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 594-4543
Email: jp149d@nih.gov

Rheumatic Diseases

Dr. Susana A. Serrate-Sztein
45 Center Drive, Room 5AS-37G
Bethesda, MD 20892-6500

Telephone: (301) 594-5032
FAX: (301) 480-4543
Email: ss86e@nih.gov

Cartilage and Connective Tissue

Dr. Bernadette Tyree
45 Center Drive, Room 5AS-37J
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 594-4543
Email: bt16w@nih.gov

Muscle Biology

Dr. Richard W. Lymn
45 Center Drive, Room 5AS-49E
Bethesda, MD 20892-6500
Telephone: (301) 594-5128
FAX: (301) 480-4543
Email: rl28b@nih.gov

Skin Diseases

Dr. Alan N. Moshell
45 Center Drive, Room 5AS-25L
Bethesda, MD 20892-6500
Telephone: (301) 594-5017
FAX: (301) 480-4543
Email: am40j@nih.gov

Bone Biology

Dr. William J. Sharrock
45 Center Drive, Room 5AS-37A
Bethesda, MD 20892-6500
Telephone: (301) 594-5055

FAX: (301) 480-4543
Email: ws19h@nih.gov

Bone Diseases

Dr. Joan McGowan
45 Center Drive, Room 5AS-43E
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: jm106v@nih.gov

Direct inquiries regarding fiscal matters to:

Sally A. Nichols
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-49F, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: sn21q@nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke free workplace and promote the non-use of all tobacco products. In addition, Public law 103-227, the pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood

development services are provided children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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